



IAP6 Rec'd PCT/PTO 23 JUN 2006 OCT

Date: June 21, 2006

I hereby certify that, on the date indicated above, I deposited this paper with identified attachments and/or fee with the U.S. Postal Service and that it was addressed for delivery to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 by "First Class Mail" service.

Kim Blum  
Name (Print)

*Kim Blum*  
Signature

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re the Application of:	DOI et al.	)	Examiner:	Unassigned
Application No.:	10/563,073	)	Group Art Unit:	Unassigned
Filed:	December 29, 2005	)	Confirmation No.:	3651
Docket No.:	3190-089	)	Customer No.:	33432

For: METHOD OF TREATING DIABETES BY INHIBITING DEGRADATION  
OF AT LEAST ONE OF CREBL1, ATF6, AND HNF-4α BY HtrA

**RESPONSE TO NOTIFICATION OF MISSING REQUIREMENTS**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

June 21, 2006

Dear Sir:

In response to the Notification of Missing Requirements Under 35 U.S.C. 371 in the United States Designated/Elected Office dated April 24, 2006, enclosed for filing is an executed Declaration for the above-identified patent application.

In the event that any fees are due with this paper, please charge Deposit Account No. 50-0925.

Respectfully submitted,

*Luke A. Kilyk*  
Luke A. Kilyk  
Reg. No. 33,251

Docket No.: 3190-089  
KILYK & BOWERSOX, P.L.L.C.  
400 Holiday Court, Suite 102  
Warrenton, VA 20186  
Tel: (540) 428-1701  
Fax: (540) 428-1720

<b>TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371</b>		ATTORNEY'S DOCKET NUMBER <b>3190-089</b>
INTERNATIONAL APPLICATION NO. <b>PCT/JP2004/14377</b>		U.S. APPLICATION NO. (If known, see 37 CFR 1.5) <b>10/563,073</b>
INTERNATIONAL FILING DATE <b>September 30, 2004</b>		PRIORITY DATE CLAIMED <b>September 30, 2003</b>
TITLE OF INVENTION: METHOD OF TREATING DIABETES BY INHIBITING DEGRADATION OF AT LEAST ONE OF CREBL1, ATF6, AND HNF-4 $\alpha$ BY HTRA		
APPLICANT(S) FOR DO/EO/US: Hirofumi DOI and Ken SAITO		
<p>Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:</p> <ol style="list-style-type: none"><li>1. <input type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a filing under 35 U.S.C. 371.</li><li>2. <input checked="" type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a filing under 35 U.S.C. 371.</li><li>3. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371 (f)). The submission must include items (5), (6), (9) and (21) indicated below.</li><li>4. <input type="checkbox"/> The US has been elected (Article 31).</li><li>5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371 (c)(2))<ol style="list-style-type: none"><li>a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</li><li>b. <input type="checkbox"/> has been communicated by the International Bureau.</li><li>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</li></ol></li><li>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371 (c)(2)).<ol style="list-style-type: none"><li>a. <input type="checkbox"/> is attached hereto.</li><li>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</li></ol></li><li>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 34 (35 U.S.C. 371(c)(3))<ol style="list-style-type: none"><li>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</li><li>b. <input type="checkbox"/> have been communicated by the International Bureau.</li><li>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</li><li>d. <input type="checkbox"/> have not been made and will not be made.</li></ol></li><li>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3))</li><li>9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</li><li>10. <input type="checkbox"/> An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</li></ol> <p><b>Items 11 to 20 below concern document(s) or information included:</b></p> <ol style="list-style-type: none"><li>11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</li><li>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</li><li>13. <input type="checkbox"/> A preliminary amendment.</li><li>14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76</li><li>15. <input type="checkbox"/> A substitute specification.</li><li>16. <input type="checkbox"/> A power of attorney and/or address change letter.</li><li>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 – 1.825.</li><li>18. <input type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154(d)(4).</li><li>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</li><li>20. <input type="checkbox"/> Other items or information:</li></ol>		

This collection of information is required by 37 CFR 1.53(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/563,073		INTERNATIONAL APPLICATION NO. PCT/JP2004/14377		ATTORNEY'S DOCKET NUMBER 3190-089	
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21. <input type="checkbox"/> The following fees are submitted:					
<input type="checkbox"/>	a) Basic national fee .....	\$300.00		\$ 0.00	
<input type="checkbox"/>	b) Examination fee .....	\$200.00		\$ 0.00	
<input type="checkbox"/>	c) Search fee .....	\$500.00		\$ 0.00	
TOTAL OF ABOVE CALCULATIONS =			\$ 1,000.00	\$ 0.00	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250.00 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra sheets	Number of each additional 50 or fraction thereof (round up to a whole number)			
54 - 100 =	0/50 =	0	x \$250.00	\$ 0.00	
Surcharge of \$130.00 for furnishing the oath or declaration later than Months from the earliest claimed priority date (37 CFR 1.492(e)).				\$ 0.00	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	19 - 20 =	0	x \$50.00	\$ 0.00	
Independent claims	5 - 3 =	0	x \$200.00	\$ 0.00	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+	\$360.00	\$ 0.00
TOTAL OF ABOVE CALCULATIONS =				\$ 0.00	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				\$ 0.00	
SUBTOTAL =				\$ 0.00	
Processing fee of \$130.00 for furnishing the English translation later than months from the earliest claimed priority date (37 CFR 1.492(f)).				\$ 0.00	
TOTAL NATIONAL FEE =				\$ 0.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				+	\$ 0.00
TOTAL FEES ENCLOSED =				\$ 0.00	
				Amount to be Refunded	\$
				Amount to be Charged	\$

a. ☐ A check in the amount of \$ \_\_\_\_\_ to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0925.

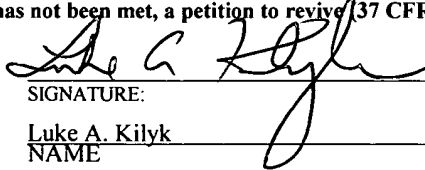
d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

**NOTE:** Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO

KILYK & BOWERSOX, P.L.L.C.  
400 Holiday Court, Suite 102  
Warrenton, VA 20186

Phone (540) 428-1701 - Facsimile (540) 428-1720

  
 SIGNATURE:  
 Luke A. Kilyk  
 NAME  
 33.251  
 REGISTRATION NUMBER

Date: June 21, 2006 I hereby certify that, on the date indicated above, I deposited this paper with identified attachments and/or fee with the U.S. Postal Service and that it was addressed for delivery to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 by "First Class Mail to Addressee" service.

Kim Blum  
Name (Print)

  
Signature



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/563,073	Hirofumi Doi	3190-089

33432  
 KILYK & BOWERSOX, P.L.L.C.  
 400 HOLIDAY COURT  
 SUITE 102  
 WARRENTON, VA 20186

**RECEIVED**  
 APR 26 2006

KILYK & BOWERSOX, P.L.L.C.

INTERNATIONAL APPLICATION NO.	
PCT/JP04/14377	
I.A. FILING DATE	PRIORITY DATE
09/30/2004	09/30/2003

CONFIRMATION NO. 3651

371 FORMALITIES LETTER



\*0000000018597815\*

Date Mailed: 04/24/2006

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 12/29/2005
- English Translation of the IA filed on 12/29/2005
- Copy of the International Search Report filed on 12/29/2005
- Preliminary Amendments filed on 12/29/2005
- Biochemical Sequence Diskette filed on 12/29/2005
- U.S. Basic National Fees filed on 12/29/2005
- Priority Documents filed on 12/29/2005

DOCKED

Due Date 6/24/06  
 Dkt No 3190-089  
 By JMB

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.

**ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

INDIA L EVANS

Telephone: (703) 308-9140 EXT 212

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/563,073	PCT/JP04/14377	3190-089

FORM PCT/DO/EO/905 (371 Formalities Notice)